

TABLE 15-continued

	Ingredients	Amt/unit* (mg)
Step 2. Sustained release coat	Eudragit RS30D (dry)	7.206
	Eudragit RL30D (dry)	0.379
	Triethyl citrate	1.517
	Cabosil	0.379
Step 3. Seal coat	Opadry Clear	1.899
	(Hydroxypropylmethyl cellulose)	
	Cabosil	0.271
Total		70.0

Process:

1. Dissolve oxycodone HCl and Opadry (HPMC) in water. Spray the drug solution onto non-pareil beads in a fluid bed coater with Wurster insert.
2. Disperse Eudragit RS, Eudragit RL, triethyl citrate, and Cabosil in water. Spray the dispersion onto the beads in the fluid bed coater.
3. Dissolve Opadry in water. Spray the solution onto the beads in the fluid bed coater.
4. Cure the beads at 60° C. for 24 hours.

One or more aversive agents as described herein can be incorporated into a capsule with the oxycodone beads, into the oxycodone beads, or on the oxycodone beads by one skilled in the art. The one or more aversive agents may be in releasable, non-releasable, or substantially non-releasable form or a combination thereof. Preferably, when beads comprising the aversive agent(s) are incorporated into the capsule they are indistinguishable from the oxycodone beads.

EXAMPLE 16

Controlled Release Hydromorphone

A sustained release hydromorphone HCl formulation is prepared having the formula in Table 16 below:

TABLE 16

Ingredients	Amt/unit (mg)
Hydromorphone HCl	12.0
Eudragit RSPO	76.5
Ethocel	4.5
Stearic acid	27.0
Total	120.0

Process:

1. Blend milled Stearic acid, ethocel, Hydrocodone Bitartrate, and Eudragit RSPO using a V-blender.
2. Extrude the mixture using a Powder Feeder, Melt Extruder (equipped with the 6×1 mm die head), Conveyor, Laser-mike, and Pelletizer.
Powder feed rate—4.2 kg/hr; vacuum—~980 mBar
Conveyor—such that diameter of extrudate is 1 mm
Pelletizer—such that pellets are cut to 1 mm in length
3. Screen pellets using #16 mesh and #20 mesh screens. Collect material that passes through the #16 mesh screen and is retained on the #20 mesh screen.
4. Fill size #2 clear gelatin capsules with the pellets. Range: NLT 114 mg and NMT 126 mg.

One or more aversive agents as described herein can be incorporated into a capsule with the hydromorphone pellets, into the hydromorphone pellets, or on the hydromorphone pellets by one skilled in the art. The one or more aversive agents may be in releasable, non-releasable, or substantially non-releasable form or a combination thereof. Preferably, when pellets comprising the aversive agent(s) are incorporated into the capsule they are indistinguishable from the hydromorphone pellets.

EXAMPLE 17-20

Examples 9-12 can be repeated utilizing a sufficient amount of capsaicin in place of, or in addition to the aversive agents disclosed therein.

While the invention has been described and illustrated with reference to certain preferred embodiments thereof, those skilled in the art will appreciate that obvious modifications can be made herein without departing from the spirit and scope of the invention. Such variations are contemplated to be within the scope of the appended claims.

What is claimed is:

1. An extended release abuse deterrent dosage form comprising:
 - a. a core matrix comprising a blended mixture of:
 - (a) PEO having a molecular weight of from about 300,000 daltons to about 5,000,000 daltons;
 - (b) magnesium stearate; and
 - (c) oxycodone or a pharmaceutically acceptable salt thereof;
 wherein the core matrix is heated to melt at least a portion of the PEO included in the core matrix during preparation of the dosage form; and
 - b. PEG applied onto the core matrix;
 wherein the dosage form provides extended release of the drug.

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